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## NOTICE OF ALLOWANCE AND FEE(S) DUE

7590 12/14/2009

Benjamin Aaron Adler ADLER & ASSOCIATES 8011 Candle Lane Houston, TX 77071 EXAMINER

KIM, JENNIFER M

ART UNIT PAPER NUMBER

1628 DATE MAILED: 12/14/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,770	09/19/2003	Pankaj Jay Pasricha	D6475	6393

TITLE OF INVENTION: TREATMENT OF IRRITABLE BOWEL SYNDROME AND RELATED BOWEL DISEASES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	03/15/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION NO THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THE APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FIEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

## PART B - FEE(S) TRANSMITTAL

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CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)				pap	Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, mus have its own certificate of mailing or transmission.			
7590 12/14/2009 Benjamin Aaron Adler ADLER & ASSOCIATES 8011 Candle Lane			I he Sta add trar	Cer creby certify that the tes Postal Service v cressed to the Mail asmitted to the USP	rtificatoris Fee( vith sur I Stop TO (57	of Mailing or Trans s) Transmittal is being ficient postage for fir ISSUE FEE address I) 273-2885, on the d	mission g deposited with the United st class mail in an envelope above, or being facsimile ate indicated below.	
Houston, TX 770'	/1							(Depositor's name)
								(Signature)
				L				(Date)
APPLICATION NO.	FILING DATE			FIRST NAMED INVENTOR		ATTO	RNEY DOCKET NO.	CONFIRMATION NO.
10/665,770 TITLE OF INVENTION:	09/I9/2003 TREATMENT OF IRR	ITAB	LE BOWEL SYNI	Pankaj Jay Pasricha DROME AND RELATEE	BOWEL DISEAS	ES	D6475	6393
APPLN, TYPE	SMALL ENTITY	IS	SUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSU	E FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES		\$755	\$300	\$0		\$1055	03/15/2010
EXAMIN	NER		ART UNIT	CLASS-SUBCLASS	1			
KIM, JENN	IFER M		I628	514-179000	J			
1. Change of corresponden CFR 1.363.  Change of correspon Address form PTOVSD/  Tee Address indie PTOVSD/47; Rev 03-02 Number is required.  3. ASSIGNEE NAME AN PLEASE NOTE: Unles recordation as set forth (A) NAME OF ASSIG	ndence address (or Cha 122) attached. ation (or "Fee Address" or more recent) attach D RESIDENCE DATA ss an assignee is identi in 37 CFR 3.11. Comp	nge of 'Indic ed. Us	Correspondence ation form e of a Customer		o 3 registered pater vely, le firm (having as a agent) and the nam ymeys or agents. If printed. pe) aatent. If an assign assignment.	n memb es of u no nan	p to p to see is 3dentified below, the d	ocument has been filed for
Please check the appropria	te assignee category or	catego	ories (will not be pr	inted on the patent):	Individual Co	orporat	ion or other private gro	oup entity Government
4a. The following fee(s) are submitted:    Issue Fee   Publication Fee (No small entity discount permitted)   Advance Order - # of Copies   Publication Fee (No small entity discount permitted)   Advance Order - # of Copies								
5. Change in Entity Statu  a. Applicant claims	SMALL ENTITY statu	s. See	37 CFR 1.27.	☐ b. Applicant is no lor				
NOTE: The Issue Fee and interest as shown by the re	Publication Fee (if requered of the United Sta	ired) י tes Pat	will not be accepted ent and Trademark	d from anyone other than Office.	the applicant; a regi	istered	attorney or agent; or th	ne assignee or other party ir
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PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.



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Benjamin Aaron Adler			KIM, JENNIFER M	
ADLER & ASSOCIATES			ART UNIT	PAPER NUMBER
8011 Candle Lane Houston, TX 7707			1628 DATE MAII ED: 12/14/200	9

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 370 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 370 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

## Notice of Allowability

Application No.	Applicant(s)	
10/665,770	PASRICHA, PANKA	AJ JAY
Examiner	Art Unit	
JENNIFER M. KIM	1628	

The MAILING DATE of this communication appears on the ladiums being allowable, PROSECUTION ON THE MERITS IS (OR REMoTE WHICH CONTROL OF TOL. 85) or other: ONTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. If the Office or upon petition by the applicant. See 37 CFR 1.313 and MPI	MAINS) CLOSED in this application. If not included appropriate communication will be mailed in due course. THIS This application is subject to withdrawal from issue at the initiativ
1. This communication is responsive to 8/24/2009 & 12/3/2009.	
2. The allowed claim(s) is/are 1, 4,6, 10,13 and 15.	
Acknowledgment is made of a claim for foreign priority under 35 U   a)   All   b)   Some* c)   None of the:   1.   Certified copies of the priority documents have been rerection   2.   Certified copies of the priority documents have been rerection   3.   Copies of the certified copies of the priority documents international Bureau (PCT Rule 17.2(a)).  * Certified copies not received:  Applicant has THREE MONTHS FROM THE "MAILING DATE" of this conted below. Failure to timely comply will result in ABANDONMENT of the content of the	belived.  belived in Application No  have been received in this national stage application from the minument of the stage application from the minument of the areply complying with the requirements
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.  I. A SUBSTITUTE OATH OR DECLARATION must be submitted. Not INFORMAL PATENT APPLICATION (PTO-152) which gives reason	
DCORRECTED DRAWINGS (as "replacement sheets") must be subnical including changes required by the Notice of Draftsperson's Pate 1) hereto or 2) to Paper No./Mail Date  Diminuluding changes required by the attached Examiner's Amendr Paper No./Mail Date  Identifying indicia such as the application number (see 37 CFR 1.84(c)) sh	nitted. ent Drawing Review ( PTO-948) attached ment / Comment or in the Office action of
each sheet. Replacement sheet(s) should be labeled as such in the header  DEPOSIT OF and/or INFORMATION about the deposit of BIC attached Examiner's comment regarding REQUIREMENT FOR THE	DLOGICAL MATERIAL must be submitted. Note the
Attachment(s) .	5. Notice of Informal Patent Application 6. Interview Summary (PTO-413), Paper No./Mail Date 7. Examiner's Amendment/Comment 8. Examiner's Statement of Reasons for Allowance 9. Other
/JENNIFER M KIM/ Primary Examiner, Art Unit 1628	

## EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Benjamin Adler on December 3, 2009.

The application has been amended as follows:

## IN THE CLAIMS:

Claims 2, 3, 5, 7-9, 11, 12, 14 and 16-18 have been canceled without prejudice.

Claim 1 has been modified to read as "A method of treating irritable bowel syndrome in an individual having the syndrome comprising the step of: administering to said individual a pharmacologically effective dose of beclomethasone with minimal or no systemic side effects."

Claim 4. line 1. delete "claim 3" and insert - - -claim 1- - -.

Application/Control Number: 10/665,770 Page 3

Art Unit: 1628

Claim 6, line 1, delete "orBec™" and insert ----beclomethasone dipropionate--

- --.

Claim 10 has been modified to read as "A method of alleviating the symptoms of irritable bowel syndrome in an individual suffering from irritable bowel syndrome comprising the step of: administering to the individual a pharmacologically effective dose of a beclomethasone with minimal or no systemic side effects such that said administration increases the threshold of pain to colorectal distention, thereby alleviating the symptoms of irritable bowel syndrome in the individual."

Claim 13 line 1, delete "claim 12" and insert - - -claim 10- - - -.

Claim 15 has been modified to read as "The method of claim 10, wherein said beclomethasone is administered in a dose of from about 0.1mg/kg to about 20mg/kg."

## Remarks

The above amendment places this case in condition for allowance.

## Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

Applicants' amendments and remarks submitted August 24, 2009 have been entered and considered. The amendments and remarks are persuasive to place the application in condition for allowance.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

## Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1628

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/ Primary Examiner, Art Unit 1628

Jmk December 3, 2009